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PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte Pu Zhou

Appeal 2008-3392
Application 10/615,651
Technology Center 1700

Decided: September 4, 2008

Before EDWARD C. KIMLIN, PETER F. KRATZ, and
CATHERINE Q. TIMM, *Administrative Patent Judges*.

TIMM, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant appeals under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1-11, 13, and 35-41. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

I. BACKGROUND

The invention relates to a method of forming a catheter. Claim 1 is illustrative:

1. A method of forming a catheter, comprising:

providing a braid layer having a distal end and a proximal end, an inner lubricious liner positioned within the braid layer;

securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end;

cutting through the braid layer and the inner lubricious liner at a cutting position proximate the distal end of the first polymer segment and removing a portion of the braid layer that extends distally of the cutting position; and

subsequent to cutting through the braid layer and the inner lubricious liner, securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position.

On review are the Examiner's rejections of:

1. Claims 1, 11, 13, and 35-41 under 35 U.S.C. § 102(e) as anticipated by Noone (US 6,591,472 B1 issued Jul. 15, 2003 to Noone et al.);
2. Claims 2-5, 7, 9, and 10 under 35 U.S.C. § 103(a) as unpatentable over Noone in view of Wilson (US 5,591,929 issued Sep. 14, 1999); and
3. Claim 6 under 35 U.S.C. § 103(a) as unpatentable over Noone and Wilson, and further in view of Zadno-Azizi (US 2004/0015150 A1 pub. Jan. 22, 2004); and

4. Claim 8 under 35 U.S.C. § 103(a) as unpatentable over Noone in view of Ashiya (US 5,947,925 issued Sep. 7, 1999 to Ashiya et al.).

Appellant argues some claims apart from the others. To the extent that the arguments are sufficiently specific to allow separate review, we consider the claims separately.

II. DISCUSSION

Anticipation of Claims 1, 11, 13, and 35-41 by Noone

Claim 1

For claim 1, the central issue is well developed by both the Appellant and the Examiner (App. Br. 7-9; Ans. 7-8; Reply Br. 2-4): has Appellant established that the Examiner reversibly erred in interpreting “over” as it is used in the context of the step of “securing a second polymer segment *over* the braid layer, the second polymer segment extending *over* the first polymer segment and extending distally of the cutting portion” as recited in claim 1?

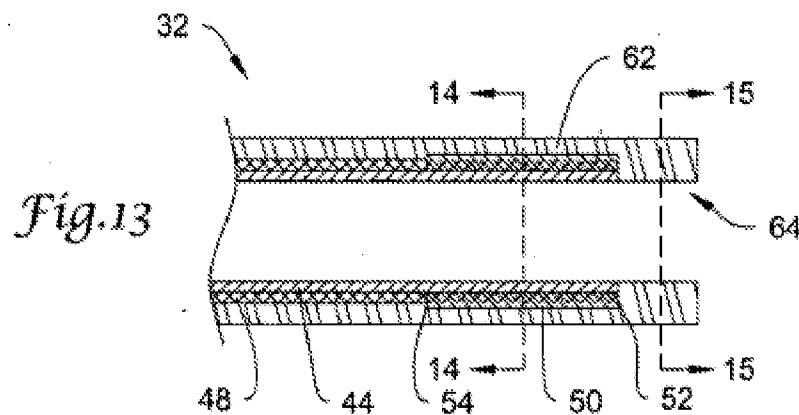
The Examiner finds that element 45, 145 of Noone (soft distal tip 45, 145) is a second polymer secured “over” the braid layer (reinforcement layer 70) and first polymer layer (distal outer layer 80) as claimed (Ans. 3).

Appellant points out that tip 45, 145 of Noone is abutted against the catheter shaft at 110 to form the distal end (App. Br. 8). Appellant contends that the Examiner’s reading of the claim to include such an abutting configuration is impermissibly broad. According to Appellant, “over” does not encompass the distal end position of Noone’s tip 45, 145, but is limited, in the art of catheters, to a location at the same position along the axis but further out radially (App. Br. 8-9; Reply Br. 2-4).

The Examiner responds that Noone's tip 45, 145 is "over" at least a cross sectional area of braid layer 70 and first polymer segment 80 as shown in Figure 8 at the cut end 110. According to the Examiner, "over" can easily be interpreted to indicate a wide variety of locations and does not necessarily require any axial component, it can mean "over" an end (Ans. 7-8).

The following Findings of Fact (FF) are particularly relevant to the resolution of the issues on appeal:

1. Appellant's catheter has a distal portion 32 shown in more detail in Figures 13-15 (Spec. 5:3-4 and 10:12-15). Figure 13 is reproduced below:



- Figure 13 reproduced above depicts an outer layer 62 in distal portion 32 that extends both radially and distally outwardly from the reinforcing braid layer 48 and securement segment 50.
2. Numerous embodiments for making the outer layer 62 are described in the Specification including embodiments in which the outer layer 62 is made from a plurality of individual segments of the same or different material (Spec. 13:22 to 14: 9).

3. In one embodiment, outer layer 62 is formed from a proximal segment 64 radially overlaying braid layer 48, intermediate segment 66 radially overlaying braid securement segment 50, and a distal segment 68 forming a distal tip (Spec. 13:23 to 14:3).
4. Figure 11 shown below illustrates the location of the proximal segment 64 to the left of intermediate segment 66, and distal segment on the right hand end (distal end) of outer layer 62.

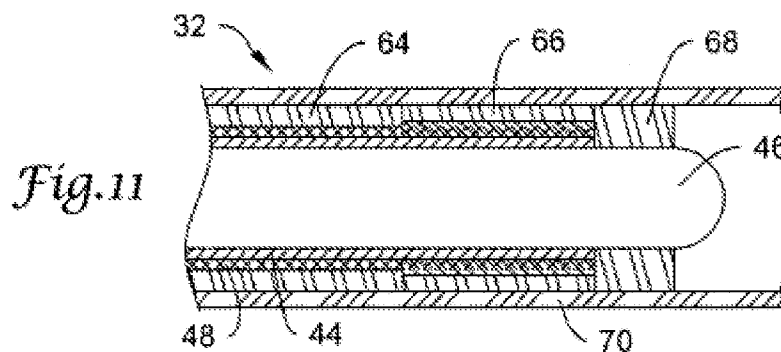


Figure 11 is reproduced above.

5. The Specification does not define or otherwise clearly disavow the plain meaning of the word “over.” (Spec. in its entirety).
6. A relevant commonly accepted meaning of “over” is “above in place or position” or “so as to rest on or cover; on or upon” (*See* dictionary.com “over”).
7. Noone describes a catheter with a discrete distal soft tip 45, 145 attached at the distal end 25 (Noone, col. 12, ll. 52-63).
8. Figure 8 of Noone as shown below illustrates the location of tip 45, 145 as covering the cut ends of distal outer layer 80 and reinforcement layer 70 (braid layer) (Noone, col. 8, ll. 49-51; col. 12, ll. 39-41).

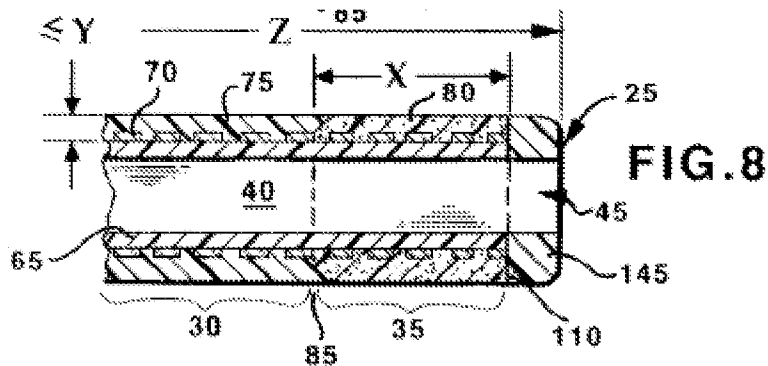


Figure 8 is reproduced above.

“[A]s an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997); *see also In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (An inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention ‘with reasonable clarity, deliberateness, and precision.’). While we consult the Specification to determine the meaning of the claim term, we take care to not limit the claim to the specific embodiments disclosed in the Specification when the term appears to have a broader meaning. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) (“[L]imitations are not to be read into the claims from the specification.”) and *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005)(en banc) (“[T]he line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms. For instance, although the

specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.”).

“To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

Considering the above principles of law, we determine that the Examiner has established that Noone anticipates claim 1.

In regard to the meaning of the claim language “securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting portion,” we note that the Specification does not define “over” such that its plain and ordinary meaning is disavowed (FF 5).

The word “over” has various meanings. When referring to position, it is used to mean “above in place or position” or “so as to rest on or cover; on or upon” (FF 6). While Appellant contends that the term has a special meaning in the catheter art, Appellant does not provide any evidence in support of this argument (App. Br. 9). Attorney argument in the briefs cannot take the place of evidence. *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974). Therefore, it is reasonable to apply the plain meaning of “over.” That meaning, as determined by the Examiner, encompasses placing the second polymer layer over *any* surface of the braid layer and first polymer segment including the end surfaces of those layers (Ans. 8). This is particularly so given that the Specification discloses different options and embodiments for layer structure (FF 1-4). This provides evidence that the

claim should not be limited to the specific embodiments of the Specification. *In re Van Guens*, 988 F.2d at 1184; *Phillips*, 415 F.3d at 1323.

We note that during patent prosecution, Appellant has the opportunity to amend the claims to obtain more precise claim coverage and when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004); *see also In re Zletz*, 893 F.2d 319, 322 (Fed.Cir.1989) ("An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process."). The Examiner has given the claims terms their broadest reasonable interpretation, and it is Appellant's burden to amend the claims to remove any uncertainties with regard to their scope.

Noone describes a catheter having a soft distal tip 45, 145 over the end of a braid layer (reinforcement layer 70) and first polymer segment (distal outer layer 80) (FF 7-8) in accordance with the Examiner's broad, but reasonable, interpretation of the claim.

Appellant has not established that the Examiner reversibly erred in interpreting "over" as it is used in the context of the step of "securing a second polymer segment *over* the braid layer, the second polymer segment extending *over* the first polymer segment and extending distally of the cutting portion" as recited in claim 1. It follows that Appellant has not established that the Examiner reversibly erred in finding claim 1 anticipated by Noone.

Claim 11

With respect to claim 11, Appellant contends that the Examiner relies upon element 75 to meet the requirements of the claim (App. Br. 10).

The Examiner responds that “75” was a typographical error and should have been “45.” (Ans. 8).

Appellant does not further address the issue in the Reply Brief (Reply Br. in its entirety).

Appellant has not established that the Examiner reversibly erred in finding tip 45, 145 of Noone meets the requirements of claim 11.

Claims 13, and 35-41

With respect to claims 13, and 35-41, Appellant does not present any arguments sufficiently specific to the limitations of those claims to allow separate review. Those claims, therefore stand or fall with claim 1.

We sustain the rejection of claims 1, 11, 13, and 35-41 under 35 U.S.C. § 102(e) as anticipated by Noone.

Obviousness of 2-5, 7, 9, and 10 over Noone and Wilson

Turning to the rejection of claims 2-5, 7, 9, and 10 as obvious over Noone in view of Wilson, Appellant presents sufficiently specific arguments for claims 2 and 3, but not for the other claims. Therefore, we confine our review to the issues arising with respect to claims 2 and 3.

Claim 2

With respect to claim 2, Appellant focuses on the limitation “wherein the first polymer segment has a melting point that is at least about 10 °F above a melting point of the second polymer segment.” (App. Br. 11.) Appellant contends that neither Noone nor Wilson teaches the desirability of

making the connection between the distal tip and the catheter by melting, Noone does not suggest or imply that the connection is made by melting, and there is no suggestion to modify the reference teachings (App. Br. 11).

The Examiner contends that Wilson shows attaching tips to catheters by welding or fusion, and Noone could reasonably use Wilson's welding or fusion to attach the second polymer segment (tip 45, 145) (Ans. 8-9).

The issue is: has Appellant established that the Examiner reversibly erred in finding a reason to weld tip 45, 145 of Noone according to Wilson's method?

The following additional Findings of Fact (FF) are relevant:

9. Noone discloses that the distal soft tip 145 "can be shaped and attached to form the distal catheter body end 25 in a manner disclosed in the above-referenced [5,509,910] patent to Lunn or the [5,545,149] patent to Brin et al. or in the above-referenced copending '241 patent application." (Noone, col. 12, ll. 58-63; col. 2, ll. 15-21).
10. In describing distal tip bonding techniques, Noone discloses that "[b]utt welding techniques are disclosed in the above-referenced '910, '416, and '149 patents." (Noone, col. 2, ll. 33-38).
11. Wilson discloses that "[c]atheters which incorporate multiple axial sections typically employ butt or lap weld joints to secure the axial sections of the catheter together (Wilson, col. 1, ll. 33-35).
12. Wilson discloses a welding technique similar to butt and lap weld techniques, but with an increased welding area compared to butt welding and without the increased diameter of lap welding (Wilson, col. 5, ll. 43-55).

13. Wilson discloses loading a thin wall sleeve 126 formed of polyester ester material onto the braid layer 122 (Wilson, col. 7, ll. 57-65 as modified by col. 9, ll. 21-36).
14. A length of soft tip material (PEBA material) in the form of a sleeve 130 is threaded over the end of a Teflon layer 120 underlying the braided layer 122 so it abuts the end of the braid layer 122 and then jacket sections 112, 114, and 116 are loaded onto the braided layer with the jacket section loaded first so it contacts the tip stock sleeve 130 (Wilson, col. 8, ll. 10-15 and 37-44).
15. The terminal tip sleeve 130 along with the jacket sections 112, 114, and 116 are covered with a shrink tube 134, the assembly placed in an oven to heat the jacket material and shrink the tube 134 so the material of the jackets compresses into the interstices of the braid layer 122 (Wilson, col. 8, ll. 50-65).
16. The polyester ester material of the thin wall sleeve 126 has a higher melting temperature than the PEBA material so the sleeve 126 does not remelt during shrinking of tube 134 (Wilson, col. 9, ll. 41-44).

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007).

Contrary to the arguments of Appellant, we find that Noone suggests attaching tip 45, 145 by butt welding (FF 9-10), i.e., a process, as acknowledged by Appellant that requires localized melting of the segments to be joined (App. Br. 11). Wilson is also directed to joining portions of a catheter by welding and is directed to solving problems created by remelting during the welding process (FF 11-16). The evidence supports the

Examiner's finding that the prior art provides a suggestion of using a higher temperature material, as taught by Wilson, in the process of Noone to prevent undesired remelting of a layer adjacent the tip during welding of the tip to the catheter end. *See KSR*, 127 S. Ct. at 1740-41 ("Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.").

Appellant has not established that the Examiner reversibly erred in finding a reason to weld tip 45, 145 of Noone according to Wilson's method.

Claim 3

Appellant points out that the Examiner's rejection is based upon the rationale that securing the first polymer segment of Noone using the heat shrink method of Wilson would have been obvious "in order to most efficiently bond the materials together." (App. Br. 11-12; *see also* Ans. 5). Appellant contends that Wilson does not suggest that the heat shrink method is most efficient, merely that it is preferable for unspecified reasons for producing the catheter of Wilson, and that because Noone teaches a continuous extrusion process that appears to be largely automatic, "Appellant is unable to see why one might modify the process of Noone et al. in view of Wilson." (App. Br. 12).

The Examiner responds that the heat shrink tube method of Wilson allows simultaneous securing of three different polymer segments referring to Wilson column 8, lines 61-65 and this is an efficient method of securing

polymer segments together relative to a method wherein various polymer segments are secured sequentially (Ans. 9).

The issue is: has Appellant established that the Examiner reversibly erred in finding a reason to apply the heat shrinking method of Wilson to form a catheter of Noone's construction?

We answer in the negative because Wilson describes an alternative method of constructing a catheter using preformed segments as opposed to coextruded segments, and the substitution of the one method for the other appears to be no more than the application of a known method to yield predictable results, i.e., the ability to join preformed segments together simultaneously rather than coextrude portions and then join a tip. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 127 S. Ct. at 1739.

Appellant has not established that the Examiner reversibly erred in finding a reason to apply the heat shrinking method of Wilson to form a catheter of Noone's construction.

We sustain the rejection of claims 2-5, 7, 9, and 10 as obvious over Noone and Wilson.

Obviousness of Claim 6 over Noone, Wilson, and Zadno-Azizi and Claim 8 over Noone and Ashiya

Appellant advances no sufficiently specific arguments directed to the Examiner's further reasons for rejecting claims 6 and 8. Therefore, the rejection of claim 6 over Noone, Wilson, and Zadno-Azizi and the rejection

of claim 8 over Noone and Ashiya are sustained for the reasons discussed above with respect to the rejection of claim 1.

III. CONCLUSION

In summary, we sustain the rejection of claims 1, 11, 13, and 35-41 under 35 U.S.C. § 102(e) and the rejections of claims 2-10 under 35 U.S.C. § 103(a).

IV. DECISION

The decision of the Examiner is affirmed.

V. TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal maybe extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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